UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/509,785 | 05/11/2005 | Hisashi Narimatsu | 3462.1010-000 | 3100 |

21005 7590 05/08/2006

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

| EXAMINER | |
|---|---|
| CHOWDHURY, IQBAL HOSSAIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/509,785 | NARIMATSU ET AL. | |
| | Examiner | Art Unit | |
| | Iqbal Chowdhury, Ph.D. | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 4-53* is/are pending in the application.

4a) Of the above claim(s) *1,4,5,8 and 10-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/05, 7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

This application is a 371 of PCT/JP/03/03846 filed on 3/27/2003.

The preliminary amendment filed on 2/21/2006 amending claims 1, and canceling claims 2-3 is acknowledged. Claims 1, and 4-53 are at issue and are present for examination.

Applicant's election with traverse of Group II, Claims 5-7 and 9, drawn to a polypeptide galactose transferase and invention (A) drawn to a protein of SEQ ID NO: 2 or nucleic acid encoding SEQ ID NO: 2 in the response filed on 2/21/2006 is acknowledged.

The traversal is on the ground(s) that there is no lack of unity and the shared technical feature is distinct from the prior art, however, examiner disagrees and finds that lack of unity exists because as stated in the previous office action that the polynucleotide encoding a polypeptide galactose tranferase of Group I, polypeptide galactose tranferase of Group II and antibody of Group III, pharmaceutical of Group IV, drug of group VIII and genetically altered animal of Group X are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to polynucleotide encoding a polypeptide galactose tranferase and this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art, which is known in the art (Ju et al.). The examiner is not sure about which shared technical feature of the claims among the groups are distinct from the prior art as contended by the applicant. Applicants also argue that Ju et al. sequence is only 25.6% identical to SEQ ID NO: 1 of the instant application (also recited Fig. 2). That is not found persuasive because Ju et al. disclosed two sequences one in JBC (examiner recited, "Cloning and expression of human core 1 beta 1, 3-galactosyltransferase, J. Biol. Chem.,

2002 January, 277(1): 178-186, see IDS) and one in PNAS, which appears to be recited by the applicant. The sequence disclosed by Ju et al. (JBC) is 100% identical to SEQ ID NO: 1 and 2 of the instant application.

Applicants also noted regarding Group X that is directed to method of screening a compound by using the transgenic animal comprising nucleic acid encoding the polypeptide and the examiner intend to confirm that the statement is correct. Because transgenic animal and method of making transgenic animal and transformed transgenic animal cell are an independent invention (Group IX), which is distinct from the Group X, drawn to a method of screening compound using transgenic animal. As restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of inventions, which are independent or distinct.

Examiner notes that there was an error in the previous office action regarding groupings of the claim 5, which is drawn to a host cell comprising nucleic acid encoding the polypeptide in Group II and also in Group I, which should be in Group I not in Group II, which has already a separate group drawn to polynucleotide. Therefore, claim 5 should be in Group I not in Group II.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1, 4-5, 8, and 10-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in communication filed on 2/21/2006.

Claims 6-7 and 9 are under consideration and are being examined herein.

### *Priority*

Acknowledgement is made of applicants claim for foreign priority JP2002-94772 filed on 3/29/2002 and JP2002-201344 filed on 7/10/2002.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins are considered non-statutory subject matter. *Diamond and Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein". For examination purpose the claim is read as such.

### *Claim Objections*

Claims 6-7 and 9 are objected to as depending from non-elected claims. Appropriate correction is required.

For the examination purpose, examiner will consider all the related limitations of claim 1 upon which claims 6-7 and 9 depends.

Claims 6-7 and 9 are objected to as encompassing non-elected subject matter. Appropriate correction is required.

Claim 1 upon which claim 6, 7 and 9 depend is objected to because of the recitation "polynucleotide that encodes a polypeptide" should be "polynucleotide encoding a polypeptide". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 upon which claim 6, 7 and 9 depend is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claim 1 recites the ""under stringent conditions", but the specification does not define what conditions constitute "stringent". While page 18 attempts to describe a stringent condition, the description encompasses conditions such as hybridizable with 40% DNA homology to SEQ ID NO: 1, which is beyond the scope of that is considered stringent in the art. Sequences with 40% homology may encode different proteins with different activities. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO: 2, a sequence must be to be included within the scope of these claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having galactose transferring activity of SEQ ID NO: 2, does not reasonably provide enablement for any polypeptide having galactose transferring activity or any polypeptide having one or more amino acid substitutions, deletions, and/or insertions to SEQ ID NO: 2 or any polypeptide having 40% identity to SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which

it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 6-7, and 9 are so broad as to encompass any polypeptide having galactose transferring activity or any polypeptide having one or more amino acid substitutions, deletions, and/or insertions to SEQ ID NO: 2 or any polypeptide having 40% identity to SEQ ID NO: 2. While claim 7 recites a method of producing polypeptide by the host cell comprising polynucleotide of SEQ ID NO: 1 and recovering the polypeptide from host cell or from culture supernatant. Claim 9 recites a pharmaceutical composition wherein the composition comprises a therapeutically effective amount of polypeptide of SEQ ID NO: 2. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptide having galactose transferring activity broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only two polypeptides.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art

would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any polypeptide having galactose transferring activity or any polypeptide having one or more amino acid substitutions, deletions, and/or insertions to SEQ ID NO: 2 or any polypeptide having 40% identity to SEQ ID NO: 2 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting galactose transferase activity; (B) the general tolerance of a polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any polypeptide residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polypeptide having galactose transferring activity or any polypeptide having one or more amino acid substitutions, deletions, and/or insertions to SEQ ID NO: 2 or any polypeptide having 40% identity to SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any polypeptide having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ju et al. (J. Biol. Chem., 2002 January, 277(1): 178-186, Epub. October 24, 2001, see IDS). Ju et al. disclose the sequence of a human protein having galactose transferring activity, which is 100% identical to SEQ ID NO: 2 of the instant application. Ju et al. further teach cloning and expression of human core 1 beta1,3-galactosyltransferase, cloning the cDNA in expression vector and expressing the protein in eukaryotic cells and isolated the protein from cell and from culture supernatant.

Claims 6-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Cummings et al. (WO04/024873 A2, priority 60/411,310 filed on 9/13/2002). Cummings et al. disclose the sequence of a human protein (SEQ ID NO: 2) of 318 amino acid residues having galactose transferring activity, which is 100% identical to SEQ ID NO: 2 of the instant application. Cummings et al. further teach cloning and expression of the polypeptide human core 1 beta1,3-galactosyltransferase, cloning the cDNA in expression vector and expressing the protein in eukaryotic cells and isolated the protein from cell and from culture supernatant.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Conclusion***

**Status of the claims:**

Claims 6-7 and 9 are pending.

Claims 6-7 and 9 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Iqbal Chowdhury, PhD, Patent Examiner
Art Unit 1652 (Recombinant Enzymes)
US Patent and Trademark Office
Rm. Remsen 2B69, Mail Box. 2C70
Ph. (571)-272-8137, Fax. (571)-273-8137
IC

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1600~~ 1652